

FlexDexTM: A Minimally Invasive Surgical Tool With Enhanced Dexterity and Intuitive Control

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This paper presents a new minimally invasive surgical (MIS) tool design paradigm that enables enhanced dexterity, intuitive control, and natural force feedback in a low-cost compact package. The paradigm is based on creating a tool frame that is attached to the surgeon's forearm, making the tool shaft an extension of the latter. Two additional wristlike rotational degrees of freedom (DoF) provided at an end-effector that is located at the end of the tool shaft are manually actuated via a novel parallel-kinematic virtual center mechanism at the tool input. The virtual center mechanism, made possible by the forearm-attached tool frame, creates a virtual two-DoF input joint that is coincident with the surgeon's wrist, allowing the surgeon to rotate his/her hand with respect to his/her forearm freely and naturally. A cable transmission associated with the virtual center mechanism captures the surgeon's wrist rotations and transmits them to the two corresponding end-effector rotations. This physical configuration allows an intuitive and ergonomic one-to-one mapping of the surgeon's forearm and hand motions at the tool input to the end-effector motions at the tool output inside the patient's body. Moreover, a purely mechanical construction ensures low-cost, simple design, and natural force feedback. A functional decomposition of the proposed physical configuration is carried out to identify and design key modules in the system—virtual center mechanism, tool handle and grasping actuation, end-effector and output joint, transmission system, tool frame and shaft, and forearm brace. Development and integration of these modules leads to a proof-of-concept prototype of the new MIS tool, referred to as FlexDexTM, which is then tested by a focused end-user group to

evaluate its performance and obtain feedback for the next stage of technology development. [DOI: 10.1115/1.4002234]

Keywords: minimally invasive surgery, laparoscopic tool, enhanced-dexterity, intuitive control, virtual center mechanism, cable transmission

1 Background: Minimally Invasive Surgery

Since the 1990s, surgery has benefited from advancements in materials, manufacturing techniques, and micromechanical technology [1], which have enabled the development of precise surgical tools and robotic devices that allow a surgeon to perform increasingly complicated procedures through a few small incisions [1–4]. These procedures, variously referred to as minimally invasive surgery (MIS), minimal access surgery (MAS), or laparoscopic surgery are characterized by the use of a small camera and thin tools introduced into the body through small incisions or ports to perform an operation that would ordinarily require more invasive direct access through a single much larger incision (Fig. 1). The benefits of MIS include reduction in trauma, blood-loss, scarring and post-operative pain for the patient, and considerable cost-savings due to shorter hospital stays, less post-surgical pain medication, faster recovery times, and reduced risks of post-operative complications [1–4].

Due to this wide range of benefits, MIS procedures have grown significantly and now impact almost all surgical specialties including endocrine, pediatric, bariatric, urologic, abdominal, gynecological, cardiothoracic, general, and orthopedics [2]. In 2007, the minimally invasive surgery market was valued at \$19.7 billion and is expected to grow at an annual rate of 9% to reach \$30.6 billion by 2012 [2,6]. This growth is also fueled in part by a continued shift toward shorter hospital stays, more outpatient surgeries, and a greater focus on training surgeons in MIS procedures. In a report released by the Center for Disease Control, an estimated 57.1×10^6 outpatient surgical procedures were performed in 2006, which represents an approximately 66% increase in such procedures since 1996 [7].

Given these market drivers, several new technological and procedural trends have emerged in MIS in the recent years. Hand-held tools have been augmented to provide enhanced dexterity to support the increasingly complex MIS procedures carried out by surgeons [3,4]. Robotic surgery, which provides even greater dexterity and precision—albeit at a much higher price, has also grown significantly [8]. Further evolution of MIS has led to the development of single incision laparoscopic surgery (SILS). SILS is performed using only one incision in the body, typically at the naval, and has been successfully conducted on the gallbladder, appendix, ovary, and colon [9]. A new approach is emerging in MIS named natural orifice transluminal endoscopic surgery (NOTES), which, as the name suggests, is performed through the body's natural orifices [10]. Even though more complex, these new approaches may allow for even faster recovery times and generally improved patient care. While the demands in MIS are becoming increasingly more challenging, the current technology remains limited in many ways as described in the following section.

2 State-of-the-Art in Minimally Invasive Surgical Tools

MIS tool technology can be broadly classified into two categories namely hand-held mechanical tools (traditional and enhanced-dexterity) and robotic surgery systems. The features, advantages, and disadvantages of each category are described below.

2.1 Hand-Held Tools. Hand-held tools represent the oldest and most common technology used in MIS. A hand-held tool typically consists of a thin, long shaft and is actuated via a scissorlike gripper at the surgeon's hand. This actuation is translated to the open/close motion of a cutting or grasping end-effector at the tool output. However, in traditional designs [11–14], the end-effector

Manuscript received January 2, 2010; final manuscript received July 16, 2010; published online September 10, 2010. Assoc. Editor: Vijay Goel.

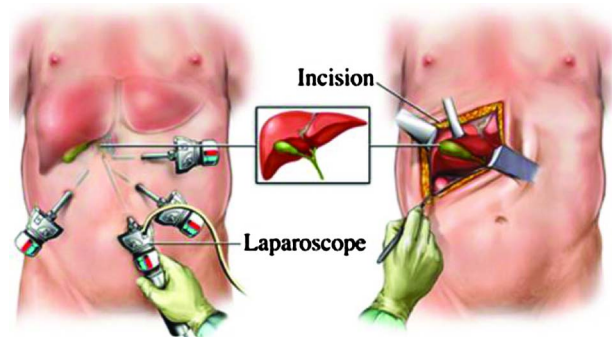


Fig. 1 Minimally invasive versus traditional surgery [5]

does not have any wristlike articulation (Fig. 2). While such purely mechanical tools are light-weight, inexpensive, and inherently provide force feedback, their lack of dexterity renders them cumbersome or ineffective for the increasingly sophisticated MIS procedures mentioned above [15].

Not surprisingly, the most significant recent technological advance in hand-held MIS tools in the recent years has been the incorporation of two additional wristlike rotational degrees of freedom (DoF) of the end-effector with respect to the tool shaft [16–22]. As a result, these “enhanced-dexterity” hand-held tools are capable of greater articulation at the end-effector while retaining the grasping action.

The RealHand™ HD from Novare [20,21] (Fig. 3) is one of the most common commercially available tools in this category. The two wristlike DoF of the end-effector at the tool output are actuated via a universal joint at the tool input. However, because of this physical arrangement, the surgeon has to provide a complex, nonintuitive combination of multiple input motions (forearm bent down and wrist bent up) to produce a simple rotation at the tool output as shown in Fig. 3. During this actuation, even though the

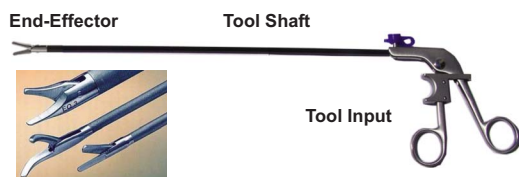


Fig. 2 Traditional hand-held tool [11]

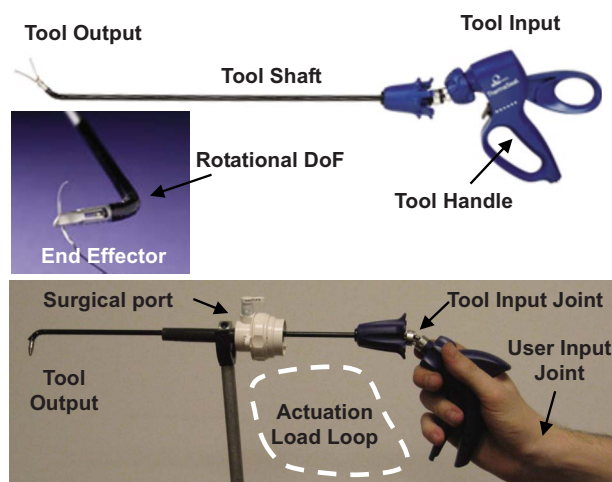


Fig. 3 Enhanced dexterity hand-held tool [20]



Fig. 4 Da Vinci surgical system [25]

tool shaft is held in its nominal position, the surgeon’s forearm is forced out of alignment with the tool shaft. As explained further in Secs. 4 and 5, this awkward input motion arises due to the fact that the tool’s input joint (i.e., universal joint) is not collocated with the surgeon’s input joint (i.e., wrist). Another enhanced-dexterity hand-held tool, the Laparo-Angle™ from Cambridge Endo [22] also employs a universal joint at the tool input and is equally difficult to operate. Also, given the “actuation load loop” shown in Fig. 3, these tools require the surgeon to exert considerable forces to actuate the tool end-effector, which may lead to surgeon fatigue and tissue trauma at the location of the surgical port in the patient’s body. This is also described further in Sec. 4.

Thus, while these enhanced-dexterity tools benefit from the abovementioned advantages of a purely mechanical construction, their unintuitive and nonergonomic operation might limit their widespread adoption in intricate MIS procedures that involve suturing [15].

2.2 Robotic Surgery Systems. While currently accounting for a relatively small number of procedures, robotic systems are employed for a range of surgeries and continue to grow in popularity as hospitals invest in hardware and training [1,3,8]. Robotic surgery systems typically comprise a user input unit that is mechanically isolated from the output, which includes a sophisticated arrangement of highly articulated robotic arms equipped with mechanical tools and end-effectors. The surgeon’s hand and finger motions are captured by electronic sensors; this information is transmitted to a computer, which controls the several actuators on the robotic arms so as to translate the surgeon’s input motions to the end-effector inside the patient’s body. Such a computer-controlled system offers several outstanding features including high dexterity enabled by the multi-DoF robotic arms, a highly intuitive input-output motion mapping, variable motion scaling, and unprecedented hand-tremor reduction [23]. The da Vinci® surgical system (Fig. 4) by Intuitive Surgical is one of the most developed robotic systems on the market in this category [24–27] and the only one to be approved by the U.S. Food and Drug Administration (FDA), at present, for minimally invasive prostatectomies [28].

Despite the numerous advantages listed above, one of the key drawbacks of current robotic systems is the lack of force feedback. Since there is no direct or mechanical connection between the system's input and output, the surgeon receives no feedback of how much force is applied while performing a procedure. While considerable research is being conducted to incorporate force and other haptic feedback via sensors in robotic surgery systems [29–33], none of these technologies have yet been integrated in commercially available products, given their associated cost and complexity.

More importantly, the size and high cost of robotic systems greatly limit their widespread use. The da Vinci system initially costs \$1.5 million and each surgery uses up to \$2000 in parts [24]. Furthermore, given the relatively large size of robotic arms in these systems, the variety of surgical procedures that may be performed is restricted due to limited accessibility and maneuverability inside the patient's body [34]. Even though some clinical reports on prostatectomy [35] indicate the benefits of robotic surgery in terms of dexterity, intuitive control, and visualization, the burden of training and additional credentialing, room setup time, and robot access remain barriers to a wider adoption of this technology [36].

3 Need for New Technology and Problem Specification

Given its continual growth and increasing complexity, minimally invasive surgery would benefit from a technology solution that simultaneously provides enhanced dexterity in terms of greater DoF at the end-effector, an intuitive and ergonomic means for actuating these DoF, and force feedback, all in a low-cost and compact package. A tool technology that meets all of these requirements could significantly ease the learning curve currently associated with MIS, especially in tasks such as suturing and knot-tying. However, it is evident from the above prior art summary that while the existing MIS tool technologies embody one or more of these desired attributes, a single solution that meets all these requirements is presently missing. Existing hand-held tools are lightweight, inexpensive, and provide force feedback but either lack the necessary dexterity or intuitive control. Robotic systems provide adequate dexterity and are intuitive to operate but lack force feedback proves to be too bulky for certain procedures, require considerable setup time, and are very expensive.

This gap in technology provided the motivation for the development of FlexDex™. Based on the above observations and discussions with several surgeons of varying specialties at the University of Michigan Health System, the following detailed list of desired attributes or system-level design requirements (DR) in a new MIS tool was compiled.

3.1 DR1: High Dexterity. In terms of functionality, high dexterity or adequate DoF is the foremost requirement. In addition to the standard five DoF (three translations, roll rotation, and grasping) provided by traditional hand-held tools, it is necessary to incorporate wristlike articulation at the tool end-effector with respect to the tool shaft via two additional DoF (pitch and yaw rotations).

3.2 DR2: Intuitive and Ergonomic Actuation. Fig. 5 shows these seven desired DoF associated with the surgeon's forearm, hand, and fingers at the tool input and the corresponding seven DoF of the end-effector at tool output. An intuitive or natural control of the end-effector can be achieved if each of its DoF is individually mapped to and actuated via the corresponding DoF of surgeon's forearm/hand/fingers. We refer to this decoupled mapping from the input to the output, i.e., a given input DoF at the surgeon's end produces only the corresponding output DoF at the end-effector, as one-to-one DoF mapping. Such a mapping, which does not exist in the current enhanced-dexterity tools (Fig. 3), would greatly facilitate an intuitive and natural use of the tool by a surgeon. In addition to a one-to-one motion mapping, it is also important to allow unrestricted input motions at the surgeon's

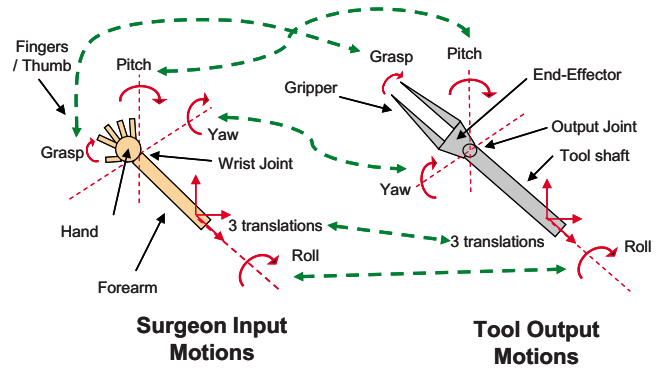


Fig. 5 One-to-one DoF mapping between the surgeon's input motions and tool output motions

forearm, hand/wrist, and fingers/thumb. In other words, the tool design should not impose any range limitations or other kinematic constraints on the input motions provided by the surgeon. Finally, to reduce surgeon fatigue, the forces required to actuate the tool DoF should be minimal.

3.3 DR3: Force Feedback. Force feedback allows the surgeon to maintain precision and control during an MIS procedure. A mechanical or kinematic transmission of motions from the surgeon at the tool input to the end-effector at the tool output also ensures that at least some of the forces at the end-effector are transmitted back to the surgeon. Thus, force feedback is inherent to purely mechanical designs. However, incorporating force feedback in robotic tools leads to considerable cost and complexity due to additional sensors, actuators, and controllers. In fact, none of the existing robotic surgery systems incorporate force feedback due to this reason.

3.4 DR4: Tight Workspace. To enable intricate surgical tasks such as suturing and knot-tying, it is important that the MIS tool end-effector provides a tight workspace. This translates to sharp turning radii of the end-effector with respect to the tool shaft during its yaw and pitch rotations.

3.5 DR5: Motion Scaling. Since MIS procedures often involve much smaller workspaces than traditional open surgeries, an MIS tool that can scale up or down the end-effector motion depending on the workspace and nature of the procedure would provide additional flexibility and utility in an operating environment. For example, translating a 30 deg hand rotation to a 10 deg end-effector rotation could provide greater precision while doing the reverse could provide a greater work-range. Ideally, the MIS tool should provide multiple transmission ratios.

3.6 DR6: Hand Tremor Reduction. The degree of precision and scale at which surgery is performed is often limited by natural tremors in the surgeon's hand. It is, therefore, desirable to minimize these tremors via the MIS tool design, so as to enable a wider range of procedures. While robotic tools can prevent transmission of the surgeon's hand tremors to the tool-effector using computer control, a relatively lesser degree of tremor suppression may be achieved in mechanical hand-held tools due to frictional damping in the motion transmission system.

3.7 DR7: Modularity and Adjustability. Modularity in terms of interchangeable tool tips can improve the utility and versatility of an MIS tool. A modular tool design also provides flexibility with respect to sterilizability and material compatibility. It is also important that the same size tool accommodates a range of surgeon hand sizes, hand preference (left or right), and gender so as to maximize its utility and minimize manufacturing costs.

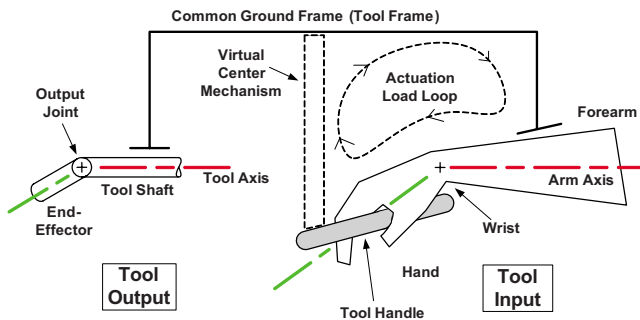


Fig. 6 Proposed hand-held MIS tool configuration

3.8 DR8: Simple and Low-Cost Construction. A simple, compact, and lightweight design and construction not only allows better maneuverability and accessibility in MIS procedures but it also provides for lower manufacturing and assembly costs. The latter is critical for commercial viability and market penetration. Furthermore, the tool design and construction should be such that it is easy and time-efficient to use/handle during a surgical procedure.

The above list of system-level DR represent the problem specification for the MIS tool design presented in this paper. As such, this problem specification lacks quantification because it is based on a high-level review of the limitations of the existing technology and on qualitatively expressed surgeon preferences. However, such a list of design requirements is still highly relevant, because at this initial stage we are primarily concerned with exploring and creating a paradigm shift that can meet these requirements, at least in principle. In the following sections, such a design paradigm and a resulting proof-of-concept prototype will be discussed. Evaluation of this prototype from an engineering as well as clinical perspective should lead to detailed, quantified design specifications for the alpha and beta phase prototype development, which is planned for the future.

4 Proposed MIS Tool Design Paradigm and Physical Configuration

To ensure a simple and affordable design (DR8), a mechanical hand-held tool configuration was adopted from the onset. This would also inherently provide a certain degree of force feedback (DR3). However, achieving the remaining design requirements in a single mechanical tool is not a trivial task as is seen in the current generation of enhanced-dexterity hand-held MIS tools described in Sec. 2.1. To overcome these limitations, a fundamental departure from this existing MIS tool design paradigm is needed. As a starting point, it may be noted that since the tool shaft is a physical analog of the surgeon's forearm (see Fig. 5), there are several advantages associated with mechanically connecting it to the surgeon's forearm. As shown in Fig. 6, a common ground frame that bridges the tool shaft and surgeon's forearm directly translates the surgeon's forearm motions (three translations and one roll rotation) to the tool shaft. This leaves the surgeon's hand and wrist free to actuate the two end-effector rotations, neatly decoupled from the other four DoF. Having achieved this decoupling, the next objective is to allow the surgeon's hand to rotate freely and naturally about the surgeon's wrist, which requires that the tool input joint and surgeon's input joint (i.e., wrist) be coincident. This is obviously nontrivial since it is impossible to collocate a "real" tool input joint with a human wrist due to physical interference. However, this challenge may be overcome by employing a concept we term the virtual center (VC) mechanism. A VC mechanism does not require the physical space occupied by the surgeon's wrist; instead, it can be designed to project a two-DoF "virtual" joint or center of rotation at the surgeon's wrist. By providing a common reference ground for the surgeon's hand and

the tool handle, which is held in the surgeon's hand, the proposed physical configuration facilitates a VC mechanism between the tool frame and tool handle. Without this common ground reference, a VC mechanism would not be possible.

The motion of the tool handle (and, therefore, the surgeon's hand) with respect to the common ground frame (and, therefore, the surgeon's forearm) may then, in principle, be captured and transmitted to the end-effector, thus, providing an entirely intuitive and natural actuation. The handle may also be equipped with a thumb lever, the motion of which is transmitted to the grasping motion of the end-effector. The effectiveness of these tasks will obviously depend on the actual embodiment of the VC mechanism and associated transmission system used (discussed in the next section). However, it is clear that enhanced dexterity, i.e., seven DoF (three translations, three rotations, and one grasping action), can be achieved, as required in DR1. Furthermore, this overall design paradigm and associated physical configuration also ensure that when only a wristlike rotation is needed at the end-effector, the surgeon only actuates his/her wrist at the tool input and the surgeon's forearm remains aligned with the tool shaft. Similarly, when a translation or roll rotation of the end-effector is needed, the surgeon simply has to provide the corresponding motion at his/her forearm. Finally, when an open/close motion of the end-effector jaws is needed, the surgeon only has to produce a grasping motion via his/her fingers and thumb. This provides the basis for the one-to-one motion mapping of the surgeon's input DoF to the corresponding output DoF of the end-effector, as required in DR2. The MIS tool physical configuration resulting from the proposed paradigm is such that the tool simply becomes a natural extension to the surgeon's forearm and hand, which is markedly different from present hand-held tool configurations.

Also, because the surgeon's forearm is now rigidly connected to the tool frame via the common ground frame, the load loop associated with the yaw and pitch rotation actuation is locally closed between the surgeon's forearm, hand, tool handle, VC mechanism, and the tool frame. In marked contrast with the existing hand-held tools, this entirely eliminates the need for an external ground reference, such as the surgical port to provide reaction loads. This should greatly reduce the actuation effort on the part of the surgeon and the forces exerted on the patient's body, further satisfying DR2.

Thus, at least qualitatively, one can rationalize that the most critical design requirements (DR1–DR3 and DR8) can be met. Meeting the remaining design requirements depends on the specific embodiment and detailed design of the various modules and components involved. Based on the proposed design paradigm and associated physical configuration, we proceed to develop a novel hand-held MIS tool, referred to as FlexDex™ with the objective of meeting all the DR listed in the previous section.

5 Detailed Design and Implementation

The detailed design and hardware implementation of the proposed design paradigm is carried out by first conducting a hierarchical functional decomposition to identify key modules in the system. These modules are individually developed while keeping in mind the overall system integration requirements. The following list is representative of the primary functions in FlexDex™ design and associated hardware modules to meet these functions. The final resulting proof-of-concept prototype is shown in Fig. 7 to introduce the terminology used in this section.

5.1 VC Mechanism and Transmission Input. The VC mechanism represents the most important innovation in FlexDex™. The challenge associated with a traditional joint (e.g., a two-DoF universal joint) at the tool input is that it cannot be made to coincide with the surgeon's wrist due to physical interference as illustrated in Fig. 8(a). To overcome this challenge, a constraint-based design approach [37] is employed to generate a novel parallel-kinematic VC mechanism, shown in Fig. 8(b),

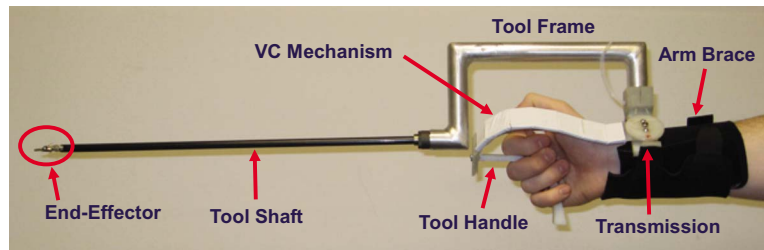


Fig. 7 FlexDex™: proof-of-concept prototype

which projects a two-DoF virtual center of rotation for the tool handle at the surgeon's wrist. In this construction, the tool handle is connected to a "pitch transmission strip" and a "yaw transmission strip," which are oriented orthogonal with respect to each other. These two transmission strips, in turn, are pivoted to the tool frame about respective shafts along the pitch and yaw axes. The point at which the two extrapolated pivot axes intersect provides a virtual center that is made to coincide with the surgeon's wrist. In this fashion, no physical structure needs to exist at the surgeon's wrist. Since the pitch and yaw rotation axes defined by the pin joints are fixed with respect to the tool frame, their inter-

section, which is the virtual center of rotation for the tool handle, also remains stationary with respect to the tool frame. Furthermore, since the tool frame is securely attached to the surgeon's forearm and the tool handle is held in the surgeon's hand, the above virtual center remains coincident with the surgeon's wrist at all times. This ensures that the surgeon's natural hand motion is never restricted or impeded.

It is important to note that the pitch transmission strip is stiff about the pitch axis but is compliant about the yaw axis. Therefore, it allows the transmission of only the pitch component of the rotation of the tool handle to the pitch transmission pulley while filtering out the yaw component by easily bending about the yaw axis. An analogous argument holds true for the yaw transmission strip, which strictly transmits only the yaw component of the handle rotation to the yaw transmission pulley while rejecting any pitch component. Thus, we now have a mechanical filtering arrangement such that given any arbitrary combination of yaw and pitch rotations at the tool handle made by surgeon's hand, only the yaw component is picked up by the yaw transmission pulley and only the pitch component is picked up by the pitch transmission pulley. This greatly simplifies the input motion transmission since one can now deal with two entirely independent rotations of the two transmission pulleys about their respective axes that are fixed with respect to the tool frame. A pitch transmission cable and a yaw transmission cable are then employed in conjunction with the respective pulleys to transmit the surgeon's two wrist rotations separately to the end-effector rotations. This VC mechanism and associated pulley based transmission system allows one to easily vary the pulley size to change the motion scaling from the tool input to tool output as desired in DR5. This cable-based transmission system is described in further detail in a subsequent subsection.

Furthermore, the transmission strips are chosen to be long enough such that they do not impose any geometric constraint along the tool axis, thus, accommodating a wide range of user hand sizes and satisfying DR7. This is possible because the functionality of the VC mechanism is largely independent of the transmission strip length. Optimal VC mechanism functionality requires the transmission strips to be highly compliant in bending about their thin cross-sectional dimension to minimize actuation effort, highly stiff in bending along their large cross-sectional dimension to transmit the respective rotations from the surgeon's hand/tool handle to their respective transmission pulleys, and highly stiff in the twisting direction to avoid any motion loss in this transmission. These attributes are met by transmission strips comprised of an alternating series of short compliant segments (acting like flexural pivots) and long rigid segments. This construction may be seen in the proof-of-concept prototype (Fig. 7), which validates the abovedescribed VC mechanism and its benefits.

5.2 Tool Handle and Grasping Actuation. The tool handle provides the interface between the surgeon's hand and the VC mechanism and is designed to be comfortable and ergonomic. In addition to being a mechanical interface to the VC mechanism, the

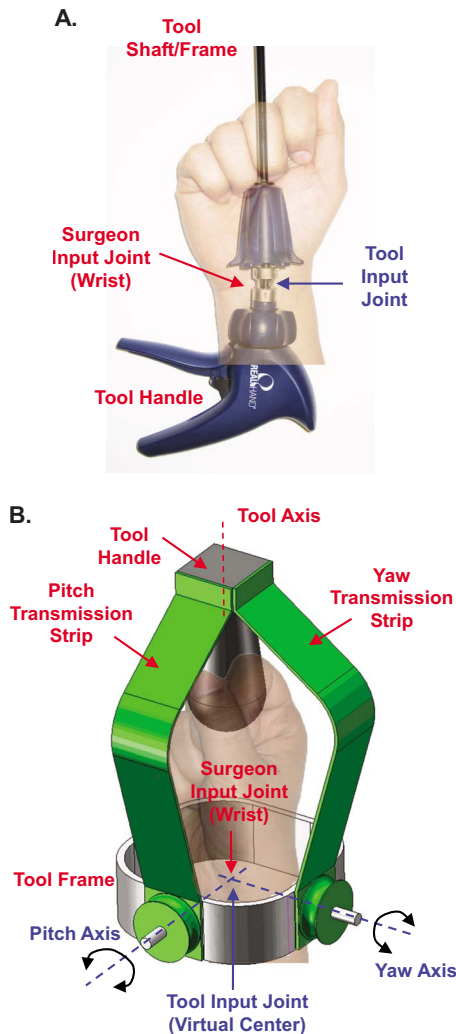


Fig. 8 Surgeon wrist versus tool input joint: (a) collocation not possible due to physical interference and (b) collocation made possible by a VC mechanism

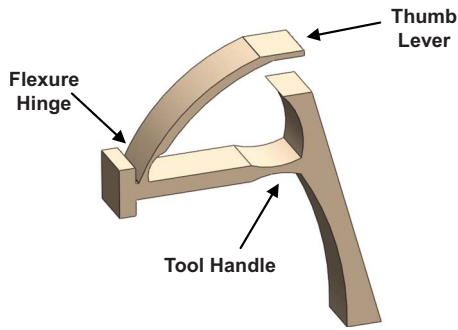


Fig. 9 Tool handle and gripper actuation

handle design also supports a means for actuating the grasping motion (e.g., gripping) of the end-effector. The tool handle design employed in FlexDex™ is relatively simple (Fig. 9) but carefully takes into consideration ergonomics studies and guidelines for MIS tools [38,39]. The handle is slanted at a 17 deg angle to fit the typical natural angle of the hand at its neutral position [40].

For actuating the gripping motion of the end-effector, the handle is augmented with a thumb lever rather than the more common scissor-style actuation because the thumb provides higher forces and generates less tension in the wrist during use [40]. As shown in Fig. 9, the thumb lever and tool handle are made monolithic by incorporating a thin flexure hinge that allows a simple relative motion between the two. A cable-based transmission (described later) relays the thumb lever actuation at the tool input to the open/close motion of the end-effector at the tool output.

5.3 End-Effector and Output Joint. The tool output in the FlexDex™ design comprises an end-effector, capable of open/close motion, connected to the tool shaft by means of a two-DoF rotational output joint. One of the key module-level design requirement associated with the end-effector is that its output joint has to be integrated with the wrist motion transmission system and its open/close motion has to be integrated with the grasping motion transmission system. A novel nested ring output joint concept (Fig. 10) is employed in the FlexDex™ to produce large and decoupled rotations (yaw and pitch) of the end-effector with respect to the tool shaft.

Decoupling the two wristlike rotational DoF at tool output is as important as doing so at the tool input to meet the ultimate objective of one-to-one motion mapping between the input and output (DR2). Existing output joint designs are either based on a snake-

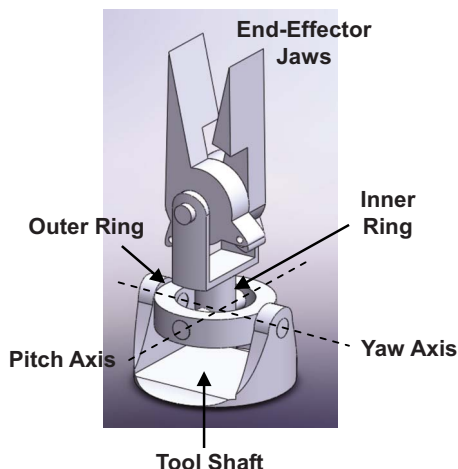


Fig. 10 Nested ring output joint and end-effector

like configuration [20–22,41] or a two-hinge arrangement [27]. The snakelike design comprises an axial stack of multiple disks serially hinged to each other, where the hinge axes alternate between the yaw and pitch rotational directions. Transmission cables routed through peripheral holes on the disks cause the stacked-disk arrangement to bend along the yaw or pitch rotational axes. While simple in design and construction, this design produces a relatively large radius of curvature because the rotation allowed between consecutive disks is generally small. This generally does not provide the desired tight workspace (DR4) and, therefore, may preclude certain intricate MIS procedures that require sharp end-effector turns.

Although more complex in construction, designs based on a pair of orthogonal cascaded hinges (e.g., a traditional two-DoF universal joint) do allow large rotations in very tight workspaces. Cables interfaced with these hinges provide the necessary actuation along the two-hinge axes. However, due to space constraints in many existing designs such as the EndoWrist™ tool [27] used in da Vinci Surgical Systems, the two rotational axes do not lie in the same axial plane. This results in a coupling between the two rotational DoF at the end-effector, i.e., a single rotational actuation (either yaw or pitch) at the tool input produces a combination of yaw and pitch rotations at the tool output. In a robotic system, this output coupling is easily corrected by means of appropriate inverse kinematics implemented in the computer controller. However, this is obviously not possible in purely mechanical designs such as the FlexDex™.

To provide a tight workspace and at the same time eliminate the abovedescribed output motion coupling, we have developed a two-hinge output joint in the FlexDex™ such that the two rotational axes lie in a common axial plane (Fig. 10). An outer ring is pivoted with respect to the tool shaft about a yaw axis. An inner ring is pivoted with respect to the outer ring about a pitch axis, such that the yaw and pitch axes are orthogonal and coplanar. The inner ring is also rigidly connected to end-effector. The two ends of the yaw transmission cable are attached at two diametrically opposite points on the outer ring along the pitch axis. Similarly, the two ends of the pitch transmission cable are attached at two diametrically opposite points on the inner ring that line up along the yaw axis. Thus, the two rotational DoF as well as their associated transmissions are largely decoupled over an acceptable range of rotation (± 60 deg). The gripping motion transmission cable passes through the inner ring and is attached to the end-effector jaws to produce an open/close gripping motion in response to the thumb lever actuation at the tool input.

5.4 Transmission System. A cable-based transmission system from the tool input to the tool output is ideally suited for FlexDex™ given the narrow bore of the tool shaft that passes through the patient's body. At the tool input, the fixed-axis VC mechanism captures the two rotations of the tool hand (and the surgeon's hand) into well-defined separated-out rotations of the yaw and pitch pulleys. At the tool output, the yaw and pitch rotations are well-defined via the respective hinges. Cables are wrapped around the transmission pulleys at the tool input and attached to the appropriate rings at the tool output. During the overall tool assembly, care has to be taken to align the yaw and pitch rotational axes of the transmission pulleys at the tool input with the corresponding yaw and pitch rotational axes defined by the hinges at the tool output. Although a minor step, this is necessary to ensure the desired one-to-one motion mapping.

A cable-based transmission is also used to relay the actuation of the thumb lever to the corresponding open/close motion of the end-effector jaws. Cables threaded through cable-sheaths provide for an easy routing through the tool frame and the tool shaft. Such a cable sheath arrangement is particularly effective for the grasping motion transmission because the tool handle, where the thumb lever is mounted, is not fixed with respect to the tool frame. Teflon tubes (19 gauges) are used as low friction cable sheaths and Kevlar is used for the transmission cables.

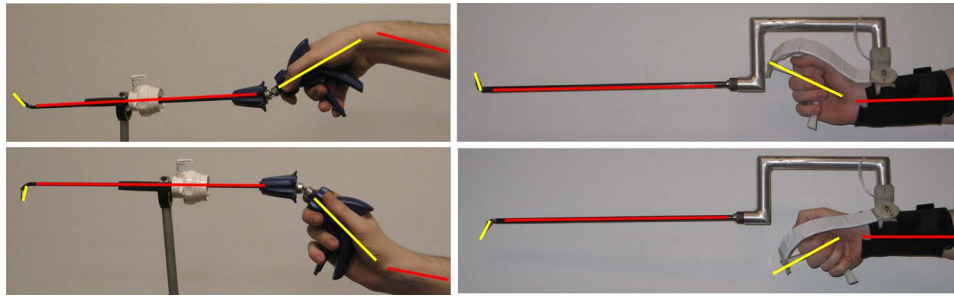


Fig. 11 Existing enhanced-dexterity MIS tool (left) versus FlexDex™ (right)

The fixed-axis VC mechanism described earlier and associated cable and pulley based transmission system offer the ability to easily vary the transmission pulley sizes to change the motion scaling from the tool input to tool output, as desired in DR5. In the future, appropriate features may be easily built into this design such that input-output motion scaling can be either discretely or continuously varied by the user.

As mentioned earlier, the transmission of the translational and roll rotational motions of the surgeon's forearm are directly transmitted to the end-effector via the tool frame that is attached to the surgeon's forearm. Thus, the completely mechanical nature of motion transmission from the tool input to tool output for each DoF also implies that any forces experienced by the end-effector are similarly transmitted back to the surgeon's hand (in case of yaw and pitch rotations), thumb (in case of grasping), and forearm (in case of translations and roll rotation). This helps satisfy DR3.

Finally, friction and damping between the mechanical components in this cable-based transmission system will likely provide some hand-tremor reduction as required by DR6. However, this can never match the efficiency of robotic systems, which employ filtering algorithms to eliminate the high frequency components from the electrical output of the sensors that pick up the surgeon's hand motions.

5.5 Tool Frame and Shaft. The tool frame is the basic structural element of FlexDex™. It is secured to the surgeon's forearm via an arm brace on one end and is rigidly connected to the tool shaft on the other end. It provides a common ground reference for the tool handle and VC mechanism, end-effector and output joint, and the transmission systems. Given the tool's physical configuration, the tool frame provides the path to close the actuation load loop locally. Additionally, it provides routing for the transmission cables from the tool handle to the tool shaft. The tool frame design employed in FlexDex™ is relatively straightforward, comprising a light and hollow tube shaped appropriately (Fig. 7). The frame is sized and oriented to avoid mechanical interference with the surgeon's hand or the transmission strips. In later stage prototypes, the tool frame would be optimized for compactness and minimal weight.

The tool shaft interfaces with the tool frame on one end and with the end-effector at the other end. It is typically a thin, long, and hollow tube with standardized dimensions (2 mm, 5 mm, and 8 mm) that are common across most MIS tools. In the current FlexDex™, an 8 mm carbon-fiber tube is chosen for its low weight and high rigidity. Future prototypes will incorporate smaller diameter shafts. The hollow tool frame and shaft also acts as a conduit for the transmission system from the input to output, thus, keeping all the transmission cables neatly tucked inside.

5.6 Forearm Brace. An arm brace that connects the tool frame to the surgeon's forearm is central to the proposed MIS tool design paradigm and its associated benefits. The arm brace should provide a secure yet comfortable interface between the tool frame and the surgeon's forearm. In the present FlexDex™ prototype, a soft fabric-based arm brace, internally supported by rigid plates, is

secured to the surgeon's forearm using Velcro straps (Fig. 7). This holds the tool shaft parallel and in-line with the surgeon's forearm and effectively relays the three translations and roll rotation of the forearm to the tool shaft and end-effector. Securing the tool to the forearm also poses a limitation since the surgeon may have to switch between multiple tools during an MIS procedure. Therefore, the ability to mount and release the tool in a short time and with minimal effort is of paramount importance as per DR8. In subsequent prototype development, we shall explore several snap-on/snap-off arm brace concepts that accomplish this goal.

6 Proof-of-Concept Prototype and Performance Evaluation

The detailed design, development, and validation of the above modules and their subsequent integration led to the first fully functional proof-of-concept prototype of FlexDex™ [42,43]. It is once again noted that this prototype was largely based on qualitative design requirements and not on quantified technical specifications, much of which were initially unknown until a preliminary round of end-user testing was conducted. The primary purpose of this proof-of-concept prototype was to validate that the proposed MIS tool design paradigm and associated physical configuration are indeed capable of producing the enhanced functionality of robotic tools in a simple low-cost mechanical design.

To highlight this enhanced functionality, the proof-of-concept FlexDex™ prototype is shown alongside an existing enhanced-dexterity MIS tool [20] in Fig. 11. Both tools are actuated to provide a single rotational DoF along the pitch direction at the end-effector. It is evident that to provide this output DoF, the surgeon has to generate a complex combination of input DoF in the case of the existing tool. Moreover, the directions of rotation of the surgeon's wrist and end-effector are opposite and, therefore, counterintuitive; also, the surgeon's forearm does not remain aligned with the tool shaft. However, with FlexDex™, a single upward motion of the surgeon's wrist produces an analogous motion of the end-effector, and the surgeon's forearm always remains aligned with the tool shaft. Thus, a one-to-one mapping between the surgeon's input motion and tool output motion is clearly evident. It is also important to note in this figure that while the existing tool is reliant on a surgical port, the corresponding actuation in FlexDex™ is produced without the presence of a surgical port. Thus, even though the FlexDex™ tool will pass through a surgical port during an actual operation, it will not exert any significant loads on it. All these attributes make FlexDex™ a promising alternative to current hand-held devices as well as robotic surgery systems.

To evaluate the performance of FlexDex™, a focused end-user group study involving the above prototype was conducted. Fourteen surgeons from the University of Michigan Health System representing six surgical specialties (general, pediatric, thoracic, urologic, bariatric, and endocrine) participated in this study. There was a consensus among these surgeons that compared with existing enhanced-dexterity MIS tools, the FlexDex™ prototype show

great potential to provide enhanced functionality that would allow them to complete more complex operations in a minimally invasive fashion and would likely increase the number of surgeons performing MIS cases.

7 Conclusion and Future Work

A novel MIS tool design paradigm and the resulting proof-of-concept FlexDex™ prototype presented in this paper establishes for the first time the feasibility of achieving enhanced dexterity, intuitive and ergonomic control, and force feedback in a simple mechanical tool. At this early stage of concept development and validation, the design process has been largely qualitative. As the immediate next step in this development effort, the surgeon feedback gathered in the focused end-user study will be compiled to create the quantitative design specifications for the next generation (alpha) prototype. Following a systematic clinical testing of the alpha prototype, these design specifications will be further honed and hardened in a subsequent beta prototype. We envision that upon appropriate product development and refinement, FlexDex™ could evolve to be a highly functional yet affordable alternative to existing MIS tool technologies. In particular, its unique intuitive actuation capability could potentially help reduce the learning curve currently associated with intricate MIS procedures such as suturing.

This project was supported in part through the faculty startup funds provided to the first author from the Mechanical Engineering department at the University of Michigan. The second author acknowledges a graduate research fellowship from the Mechanical Engineering department. The intellectual property associated with the FlexDex™ technology is protected by domestic and international patent applications [42].

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